

## PATENT

**REMARKS**

In the Final Office Action, claims 1, 2, 4-12, 14, and 16-22 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 5,974,341 to *Er et al.*

In the Final Office Action, claims 1, 2, 4-11, and 16-22 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,073,049 to *Alt et al.*

In the Final Office Action, claims 3, 13, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Accordingly, claims 1-22 are now pending. Following is a discussion of the patentability of each of the pending claims.

**Rejection of Claims 1, 2, 4-12, 14, and 16-22 under 35 U.S.C. §102(e) as being anticipated by *Er et al.***

Without addressing the merits of the rejection of claims 1, 2, 4-12, 14, and 16-22, in accordance with the American Inventors Protection Act, the *Er et al.* reference does not qualify as prior art for a rejection under 35 U.S.C. §102(e) because the present application has been filed on or after November 29, 2000 and the subject matter of the *Er et al.* reference and claims 1, 2, 4-12, 14, and 16-22 were, at the time the invention was made, subject to an obligation of assignment to the same organization (see section entitled "Obligation of Assignment to the Same Organization"). Accordingly, the *Er et al.* reference no longer qualifies as prior art under 35 USC §102(e).

**Obligation of Assignment to the Same Organization**

Ronald Tamura, an attorney of record for the present application, states that Application Serial Number 10/051,889 and U.S. Patent Number 5,974,341 to *Er et al.* were, at the time the invention of Application Serial Number 10/051,889 was made, owned by Pacesetter, Inc. or subject to an obligation of assignment to Pacesetter, Inc. Submitted herewith are Exhibit A, which is the recorded Assignment for U.S. Patent

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Number 5,974,341; and Exhibit B, which is the recorded Assignment for the present application Serial Number 10/051,889.

**Rejection of Claims 1, 2, 4-12, 14, and 16-22 under 35 U.S.C. §102(e) as being anticipated by Alt et al.**

**Independent Claim 5**

Claim 1 recites an implantable medical device comprising a parameter storage unit, a receiver, and a controller. The parameter storage unit is operative to store parameter data corresponding to at least two programming states. The receiver is operative to receive communication signals from an external device. The controller controls the operation of the implantable medical device according to a selected one of the programming states, wherein the controller is responsive to receipt of a reset signal by the receiver to retrieve parameter data from the parameter storage unit corresponding to another of the programming states and to implement the parameter data to change the programming state.

As stated previously in the Response dated February 18, 2004, the specification of the present application states that parameters corresponding to a particular programming session are stored together, along with any default parameters, within the pacemaker as a unique programming state. For each programming state, the memory unit stores all of the parameters for that programming state. Whenever a new programming session is initiated to modify or otherwise update the programming parameters, the modified parameters, along with previously programmed or default parameters, are stored within the pacemaker as a new programming state. Hence, in the present application, the operator can easily and conveniently reset the programming of the pacemaker to a different programming state by merely selecting the state and entering the appropriate reset commands.

The *Alt et al.* reference discloses a pacemaker adapted to be selectively upgraded after implantation to provide a plurality of different diagnostic, functional, and pacing operational modes. For example, included in the various pacing therapy modes are

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combinations of single and dual chamber sensing, pacing, and electrical response functions for treating bradycardia and pathologic tachycardia. The pacemaker is programmable to selectively enable current operations of at least one of the available pacing operational modes according to current needs of the patient while inhibiting current operation of all other available pacing operational modes and any other non-selected functional modes. Subsequently, the pacemaker may be programmed non-invasively to selectively restore operation of at least one of the inhibited pacing operational modes or other functional modes when the patient evidences a need therefore, but the selective restoration programming is locked out unless performed with a prescribed security access key. Additional charges are imposed on the patient or third party payor for the extended upgrade functions, wherein the pacemaker may be converted from an initially inexpensive and basic form to a more sophisticated form tailored to appropriate treatment and monitoring of the patient's condition. The cost of the non-invasive upgrade is considerably less than the cost of a replacement device and a surgical implant procedure.

The *Alt et al.* reference does not disclose or suggest a controller responsive to receipt of a reset signal to retrieve parameter data from the parameter storage unit corresponding to another of the programming states and to implement the parameter data to change the programming state. The *Alt et al.* reference discloses a backup reset to a full-featured pacemaker from a partial-featured mode that requires programming of an authorized upgrade code at a later date for all features to remain active. Alternatively, the pacemaker may be reset to a predetermined limited functional mode, and prompts the user to obtain upgrade codes from the manufacturer. Both options allow instantaneous restoration of critical feature for patient safety, while preventing unauthorized upgrading.

However, it appears that both reset features are limited to resetting diagnostic, functional, and pacing operational modes. Each operational mode typically comprises a plurality of individual parameter settings which may require further adjustment to meet the needs of a particular patient. Thus, resetting to a different operational mode may require further parameter adjustments, whereas claim 1 of the present application recites

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resetting to another programming state such that all parameters for the pacemaker may be reset to another programming state. As stated previously, for each programming state, the memory unit stores all of the parameters for that programming state. Whenever a new programming session is initiated to modify or otherwise update the programming parameters, the modified parameters, along with previously programmed or default parameters, are stored within the pacemaker as a new programming state. Hence, in the present application, the operator can easily and conveniently reset the programming of the pacemaker to a different programming state by merely selecting the state and entering the appropriate reset commands.

Furthermore, the *Alt et al.* reference discloses the resetting of only particular portions of a programming state, wherein particular diagnostic, functional, and pacing operational modes are reset. For example, the reset procedure described in *Alt et al.* may be limited to the resetting of a pacing operational mode. With such a reset procedure, an operator may be required to manually reset the operating parameters directed to the diagnostic and functional modes. In the present application, a change in the programming state can result in a change in all operating parameters for the implantable medical device. The change in the programming state is not limited to particular portions of the programming state such as the resetting of operating parameters directed to a pacing operation mode.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-4, 10-13, 17, and 18

Claims 2-4, 10-13, 17, and 18 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 5

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 5 is in condition for allowance.

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Dependent Claims 6-8, 14, 15, 19, and 20

Claims 6-8, 14, 15, 19, and 20 depend from claim 5 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 9

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 9 is in condition for allowance.

Dependent Claims 16, 21, and 22

Claims 16, 21, and 22 depend from claim 9 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

6/3/04

Date

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Enclosures: Exhibits A and B

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MARCH 11, 1998

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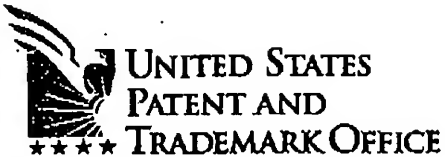
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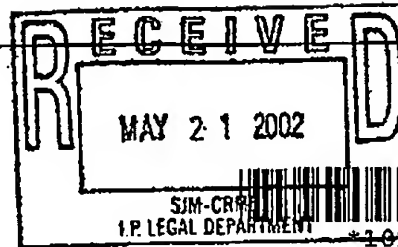
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EXHIBIT B

012694/0685 PAGE 2

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